

 182. (New) A method according to claim 149 wherein the selecting is to identify an HCV positive sample for removal from the supply.

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### REMARKS

The present Preliminary Amendment is responsive to the request for Removing the Finality of the Office Action pursuant to 37 C.F.R. § 1.129(a) mailed November 17, 2000 and further to the earlier preliminary amendments filed January 26, 2001 and April 3, 2001. Claims 88 to 104 and 106-114 are cancelled. This cancellation is not a concession that the subject matter of those claims is unpatentable, and Applicants reserve the right to pursue the subject matter of those claims in future divisional applications. Claims 115-127, 138, 144, and 154-161 are amended to correct typographical errors and to clarify the nature of the subject matter claimed. These corrections are not to overcome reasons for unpatentability. New claims 162-182 are added. Claims 115 to 182 are now pending in view of the above amendments.

Support for the newly added claims can be found in Figures 14, 58, 89 and 90 and their corresponding descriptions. The HCV cDNA library in clone ATCC 40394 is disclosed on page 255 of the Specification. Disclosure related to antigen-antibody complex formations with epitopes of claimed polypeptides can be found in section IV.G. and throughout the Specification. Hybridization of oligonucleotides and stringency of hybridization protocols are disclosed in section II.H. on pages 61-63 and throughout the Specification. ELISA and radioimmunoassays using HCV polypeptides are disclosed in section IV.I. and throughout the Specification. Evidence distinguishing Hepatitis A and B virus polypeptides is disclosed in section IV.B.3. and throughout the Specification. Preparation, isolation and sequencing of the individual HCV cDNA clones and the composite sequences derived from them are disclosed in section IV.A of the Specification. Applications of the claimed methods in preparation of blood-related products and polyclonal antibodies, and in passive immunotherapy are disclosed on page 8, page 41, in

sections II.B, G, and I and throughout the Specification. No new matter is added. Entry and consideration of the above new claims are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

If the Examiner wishes to discuss the pending claims or the application she is invited to call Applicants' attorney at the telephone number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 223002006313. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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*official***VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Claims:**

115. (Amended once) A method of [preparing] selecting biological samples from human individuals [prior to use in order to prevent transmission of hepatitis C virus (HCV)], said method comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples [one or more], [biological] samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 3.

116. (Amended once) A method of [preparing] selecting biological samples from human individuals [prior to use in order to prevent transmission of hepatitis C virus (HCV)], said method comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples [one or more], biological samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 62A.

117. (Amended once) A method of [preparing] selecting biological samples from human individuals [prior to use in order to prevent transmission of hepatitis C virus (HCV)], said method comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples [one or more], biological samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 89.

118. (Amended once) A method of [preparing] selecting biological samples from human individuals [prior to use to prevent transmission of hepatitis C virus (HCV)], said method comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples [HCV positive [biological] samples, wherein said HCV positive] samples that comprise either (i) a polynucleotide that hybridizes under stringent conditions to a polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof, or (ii) antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids encoded by a hepatitis C virus genome.

119. (Amended once) A method of [preparing] selecting biological samples from human individuals [prior to use to prevent transmission of hepatitis C virus (HCV)], said method comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples [HCV positive biological samples, wherein said HCV positive] samples that comprise either (i) a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in [the] a lambda gt-11 cDNA library deposited as ATCC No. 40394 or (ii) antibodies that form an antigen-antibody complex with an HCV polypeptide sequence of at least 10 contiguous amino acid encoded by an HCV cDNA insert in the lambda gt-11 library deposited as ATCC deposit No. 40394.

120. (Amended once) A method of [preparing] selecting biological samples from human individuals comprising[:

- (a) providing a supply of human biological samples; and

(b)] selecting from [said] a supply of human biological samples, samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure [58] 89.

121. (Amended once) A method of [preparing] selecting biological samples from human individuals comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples, samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 14.

122. (Amended once) A method of [preparing] selecting biological samples from human individuals comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples, samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the hepatitis C virus (HCV) cDNA inserts in [the] a lambda gt-11 cDNA library deposited as ATCC No. 40394.

123. (Amended once) A method of [preparing] selecting biological samples from human individuals comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples, samples that comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids found in Figure 90.

124. (Amended once) A method of [preparing] selecting biological samples from human individuals comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples, samples that comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids found in Figure 14.

125. (Amended once) A method of [preparing] selecting biological samples from human individuals comprising[:

- (a) providing a supply of human biological samples; and
- (b)] selecting from [said] a supply of human biological samples, samples that comprise antibodies that form an antigen-antibody complex with a hepatitis C virus (HCV) polypeptide sequence of at least 10 contiguous amino acid encoded by an HCV cDNA insert in [the] a lambda gt-11 library deposited as ATCC deposit No. 40394.

126. (Amended once) A method according to any of claims [117] 118-122 wherein said stringent conditions permit the formation of a stable hybrid duplex between said polynucleotide and said contiguous sequence and do not permit the formation of a stable duplex between said contiguous sequence and the genomes of Hepatitis B or Hepatitis A viruses.

127. (Amended once) A method according to any of claims [117] 115-122, 162 or 163 wherein said polynucleotide is detectable in a PCR assay.

128. A method according to claim 126 wherein said polynucleotide is detectable in a PCR assay.

129. A method according to any of claims 118, 119, and 123-125 wherein said antibodies are detectable in an ELISA or radioimmunoassay.

130. A method according to claim 129 wherein said ELISA or radioimmunoassay employs an antigen comprising said amino acid sequence made by recombinant expression.

131. A method according to claim 130 wherein said antigen is a fusion protein.

132. (Amended once) A method according to any of claims [117] 115-125, 162 or 163 wherein said biological samples are blood .

133. A method according to claim 126 wherein said biological samples are blood.

134. A method according to claim 127 wherein said biological samples are blood.

135. A method according to claim 128 wherein said biological samples are blood.

136. A method according to claim 129 wherein said biological samples are blood.

137. A method according to claim 130 wherein said biological samples are blood.

138. (Amended once) A method according to any of claims [117] 115-125, 162 or 163 wherein said biological samples are plasma.

139. A method according to claim 126 wherein said biological samples are plasma.

140. A method according to claim 127 wherein said biological samples are plasma.
141. A method according to claim 128 wherein said biological samples are plasma.
142. A method according to claim 129 wherein said biological samples are plasma.
143. A method according to claim 130 wherein said biological samples are plasma.
144. (Amended once) A method according to any of claims [117] 115-125, 162 or 163 wherein said biological samples are sera.
145. A method according to claim 126 wherein said biological samples are sera.
146. A method according to claim 127 wherein said biological samples are sera.
147. A method according to claim 128 wherein said biological samples are sera.
148. A method according to claim 129 wherein said biological samples are sera.
149. A method according to claim 130 wherein said biological samples are sera.
150. A method according to claim 132 further comprising employing biological samples that are not selected for a preparation of blood-related products.
151. A method according to claim 133 further comprising employing biological samples that are not selected for a preparation of blood-related products.



152. A method according to claim 138 further comprising employing biological samples that are not selected for a preparation of blood-related products.

153. A method according to claim 139 further comprising employing biological samples that are not selected for a preparation of blood-related products.

154. (Amended once) A method according to claim 132 [further comprising employing said] wherein said selected samples are for use in passive immunotherapy.

155. (Amended once) A method according to claim 133 [further comprising employing said] wherein said selected samples are for use in passive immunotherapy.

156. (Amended once) A method according to claim 138 [further comprising employing said] wherein said selected samples are for use in passive immunotherapy.

157. (Amended once) A method according to claim 142 [further comprising employing said] wherein said selected samples are for use in passive immunotherapy.

158. (Amended once) A method according to claim 132 [further comprising employing said] wherein said samples are for use in the preparation of [to prepare] polyclonal antibodies.

159. (Amended once) A method according to claim 133 [further comprising employing said] wherein said samples are for use in the preparation of [to prepare] polyclonal antibodies.

160. (Amended once) A method according to claim 138 [further comprising employing said] wherein said samples are for use in the preparation of [to prepare] polyclonal antibodies.

161. (Amended once) A method according to claim 142 [further comprising employing said] wherein said samples are for use in the preparation of [to prepare] polyclonal antibodies.

162. (New) A method of selecting biological samples from human individuals, said method comprising selecting from a supply of human biological samples, samples that contain a detectable polynucleotide comprising a sequence that is fully complementary to a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof.

163. (New) A method of selecting biological samples from human individuals, said method comprising selecting from a supply of human biological samples, samples that contain a detectable polynucleotide comprising a sequence that is fully complementary to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394.

164. (New) A method according to claim 132 wherein the selecting is to identify an HCV positive sample for removal from the supply.

165. (New) A method according to claim 133 wherein the selecting is to identify an HCV positive sample for removal from the supply.

166. (New) A method according to claim 134 wherein the selecting is to identify an HCV positive sample for removal from the supply.

167. (New) A method according to claim 144 further comprising employing biological samples that are not selected for a preparation of blood-related products.

168. (New) A method according to claim 135 wherein the selecting is to identify an HCV positive sample for removal from the supply.

169. (New) A method according to claim 136 wherein the selecting is to identify an HCV positive sample for removal from the supply.

170. (New) A method according to claim 137 wherein the selecting is to identify an HCV positive sample for removal from the supply.

171. (New) A method according to claim 138 wherein the selecting is to identify an HCV positive sample for removal from the supply.

172. (New) A method according to claim 139 wherein the selecting is to identify an HCV positive sample for removal from the supply.

173. (New) A method according to claim 140 wherein the selecting is to identify an HCV positive sample for removal from the supply.

174. (New) A method according to claim 141 wherein the selecting is to identify an HCV positive sample for removal from the supply.

175. (New) A method according to claim 142 wherein the selecting is to identify an HCV positive sample for removal from the supply.

176. (New) A method according to claim 143 wherein the selecting is to identify an HCV positive sample for removal from the supply.

177. (New) A method according to claim 144 wherein the selecting is to identify an HCV positive sample for removal from the supply.

178. (New) A method according to claim 145 wherein the selecting is to identify an HCV positive sample for removal from the supply.

179. (New) A method according to claim 146 wherein the selecting is to identify an HCV positive sample for removal from the supply.

180. (New) A method according to claim 147 wherein the selecting is to identify an HCV positive sample for removal from the supply.

181. (New) A method according to claim 148 wherein the selecting is to identify an HCV positive sample for removal from the supply.

182. (New) A method according to claim 149 wherein the selecting is to identify an HCV positive sample for removal from the supply.